

REMARKS

Claims 2-12 and 21-29 were pending in the above-identified patent application when last examined and are now subject to a restriction requirement. In particular, the Examiner required election of the invention of either Group I (claims 2-9 and 27-29) or Group II (claims 10-12 and 21-26.) Applicants now confirm the telephone election to have the invention of Group II examined in the present application. The election is made without traverse. Claims 2-9 and 27-29, which are directed to non-elected subject matter, are canceled.

Claim 26 was objected to because the status identified for claim 26 in Applicants' previous amendment indicated that claim 26 was an original claim, when claim 26 was actually newly introduced in the prior amendment. The above listing of the claims shows claim 26 as being "previously presented," which correctly shows the current status of claim 26. In view of this correction, Applicants request reconsideration and withdrawal of the objection to claim 26.

Claims 10-12 and 21-26 were rejected under 35 U.S.C. § 112, second paragraph. In particular, the Examiner indicated claim 10 was indefinite regarding whether the medium is intended to be part of the rapid diagnostic system and regarding the contents of the medium. In response, claim 10 is amended to more clearly recite, "a medium containing a labeling substance that comprises a persistent fluorescent structure, the labeling structure being capable of binding the persistent fluorescent structure to a target analyte when a sample ... is applied to the medium." Applicants respectfully submit that claim 10 and claims 11, 12, and 21-26, which were rejected for depending from claim 10, comply with the requirements of 35 U.S.C. § 112, second paragraph. Applicants therefore request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112.

Claims 10-12 and 21-26 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 5,837,546 (Allen) in view of U.S. Pat. App. Pub. No. 2003/0082516 (Straus). Applicants respectfully traverse the rejection.

Independent claim 10 distinguishes over the combination of Allen and Straus at least by reciting, "A rapid diagnostic test system comprising: a medium containing a labeling substance that comprises a persistent fluorescent structure, the labeling structure being capable of binding the persistent fluorescent structure to a target analyte when a sample containing the target analyte is applied to the medium."

Allen is directed to electronic assay devices and methods that employ a sample strip and detect rapid changes in sample strips to determine concentrations of analytes in samples applied to the strips. However, Allen does not disclose or suggest use of a labeling substance containing a persistent fluorescent structure.

Straus is directed to detecting replication of cells and does not disclose a rapid diagnostic system. For example, Straus in paragraph [0169] describes an exemplary test for counting microbes in water and states, "The microbes in a sample of the water ... are concentrated and immobilized by passing the liquid through a porous membrane. The membrane containing the microbes is placed on nutrient growth medium in a disposable Petri dish. The microbes are incubated at 32° C. to allow them to replicate and to form microcolonies. Light is directed at the surface of the membrane causing cells in the microcolonies to autofluoresce. ... The autofluorescing microcolonies are then imaged electronically. ... The number of autofluorescing microcolonies is immediately calculated by image processing software and reported to the user." Straus thus describes a detection system using or requiring growth of microbe colonies.

Straus does disclose use of a variety of fluorescent materials including persistent fluorescent structures such as quantum dots. However, the combination of Allen and Straus fails to suggest use of persistent fluorescent structures in a rapid diagnostic system because it would not have been obvious in view of Allen and Straus that substances and techniques employed for tests involving cell growth would be applicable or useful in a rapid diagnostic test. Accordingly, claim 10 is patentable over the combination of Allen and Straus.

Claims 11, 12, and 21-26 depend from claim 10 and are patentable over the combination of Allen and Strauss for at least the same reasons that claim 10 is patentable over Allen and Straus.

Claim 11 recites, "a reusable module having a receptacle into which the single-use module can be inserted for communication of test signals between the single-use module and the reusable module," which in combination with claim 10 reciting, "the photodetector and the medium are contained in a single-use module" further distinguishes over the combination of Allen and Straus.

Allen is primarily directed to a single-use test system but also discloses an embodiment where portions of a test system are reused. For example, Allen beginning at column 7, line 45 states, "One of the key features of this invention is the inexpensive cost of the device such that it becomes economically practical for the device to be used as a single, disposable unit. The device includes an electronic component, a chemistry reagent

component, and a housing which contains the electronics and chemistry. It is desirable that the electronics and housing are integrated into a single piece. However, the reagent strip can be replaced once or several times such that the electronics component is re-used." Accordingly, Allen discloses an embodiment with a re-usable portion. However, the re-usable portion includes the electronics, and the single-use portion includes the test strips. Allen fails to disclose or suggest a single use module that includes a photodetector and plugs into a receptacle of a reusable module.

The combination of Allen and Strauss still fails to suggest a single use module that includes a photodetector and plugs into a receptacle of a reusable module because Strauss is not directed to a rapid test system and Strauss fails to disclose or suggest a single-use module including a photodetector. Accordingly, claim 11 further distinguishes over the combination of Allen and Strauss.

For the above reasons, Applicants request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

Claims 30-36 are added. New claims 30 and 31 depend from claim 10 and are patentable for at least the same reasons that claim 10 is patentable. New independent claim 32 is patentable at least for reciting, "a single-use module including: ... a photodetector positioned to measure light from a test area of the medium; and a reusable module including: a receptacle into which the single-use module can be inserted for communication of electrical test signals." New claims 33-36 depend from claim 32 and are patentable for at least the same reasons that claim 32 is patentable.

In summary, claims 2-12 and 21-29 were pending in the application. This response cancels claims 2-9 and 27-29, amends claim 10, and adds claims 30-36. For the above reasons, Applicants respectfully request allowance of the application including claims 10-12, 21-26, and 30-36.

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